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AT-LARGE WHIP

December 2, 1999

Dr. Jane E. Henney
Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

RE: Docket # 97N-484S

Dear Dr. Henney:

As you know, the Food and Drug Administration has proposed a new rule on reproductive tissue donations. I am writing to urge the Department to amend this proposed rule to allow all recipients of directed sperm donation to waive the six-month quarantine period providing a written waiver is signed.

It is my understanding that the proposed FDA rule would place new restrictions on sperm donation from men who have sex with men (MSMs). Sperm donations from MSMs would need to be frozen and quarantined for six months to provide for HIV and other testing of the donor. This requirement would apply in the case of "directed" donations, when the woman recipient knows the sperm donor. There would be an exception to the quarantine period if the donor and recipient are sexually intimate.

I urge you to amend the proposed rule to allow all recipients of directed sperm donation to waive the six-month quarantine period if the recipient signs a written waiver. Without such a change, the proposed guidance will effectively deny access of many donors and recipients to the medical services available at fertility clinics and sperm banks. The sperm of many potential donors will not survive the six month quarantine period, forcing donors and recipients to forgo valuable services they could receive in a clinic.

The decision about whether accept the potential risks associated with no quarantine period should be made by a potential recipient, and not a federal agency. This is an important reproductive rights issue. A woman may wish to select a specific donor, who could be effectively unavailable if his sperm has to go through a test-freeze-retest protocol. The proposed guidelines would bar the donation of fresh sperm from any relative of any woman's spouse or partner, as well as all non-intimate friends of the prospective recipient.

In addition, the FDA's proposed rule would impose limits on thousands of gay men based solely

on their membership in a group, rather than their actual HIV status. In a time when technology will soon provide for rapid assessment of HIV status based on actual infection rather than presence of anti-bodies, it seems inappropriate to dictate limits on an important life activity based only on a person's group membership (i.e. MSM) rather than their actual HIV status. Allowing direct donation with voluntary waiver of quarantine period is a safe and reasonable way to allow these donations to occur.

Thank you for your attention to these concerns.

Sincerely,

Nancy Pelosi

NANCY PELOSI
Member of Congress